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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/559,701	12/06/2005	Catherine Abbadie	21156YP	1960

210 7590 12/04/2009

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EXAMINER	
PAGONAKIS, ANNA	

ART UNIT	PAPER NUMBER
1628	

MAIL DATE	DELIVERY MODE
12/04/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/559,701	ABBADIE ET AL.	
	Examiner	Art Unit	
	ANNA PAGONAKIS	1628	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 November 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 2* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-2* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's arguments filed 11/23/2009 have been fully considered. Rejections not reiterated from previous Office Actions are hereby withdrawn. The following rejections are either reiterated or newly applied. They constitute the complete set of rejections presently being applied to the instant application.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 2 and 4 remain rejected under 35 U.S.C. 102(e) as being anticipated by Jaio et al (U.S. 7,230,008).

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

The claims encompass administering the elected compound to any patient for the prevention of neuropathic pain (as defined in page 3 of the specification). In order to prevent one must necessarily administer before the presence of disease and therefore administration of the elected compound in any patient population would then prevent neuropathic pain.

Jaio et al. teaches the administration of the elected compound for the treatment of inflammatory and immunoregulatory disorders (abstract and claims 1, 4-5 and 8-11).

Claims 2 and 4 remain rejected under 35 U.S.C. 102(e) as being anticipated by Jaio et al (U.S. 6,812,234).

The claims encompass administering the elected compound to any patient for the prevention of neuropathic pain (as defined in page 3 of the specification). In order to prevent one must necessarily administer before the presence of disease and therefore administration of the elected compound in any patient population would then prevent neuropathic pain.

Jaio et al. teaches the administration of the elected compound for the treatment of inflammatory and immunoregulatory disorders (column 14 and claims 1-24 and 25-27).

Claims 2 and 4 remain rejected under 35 U.S.C. 102(e) as being anticipated by Goble et al (U.S. 7,393,844).

The claims encompass administering the elected compound to any patient for the prevention of neuropathic pain (as defined in page 3 of the specification). In order to prevent one must necessarily administer before the presence of disease and therefore administration of the elected compound in any patient population would then prevent neuropathic pain.

Jaio et al. teaches the administration of the elected compound for the treatment of inflammatory and immunoregulatory disorders (column 14 and claims 1-22).

Claims 2 and 4 remain rejected under 35 U.S.C. 102(e) as being anticipated by Jaio et al (U.S. 7,166,614)

The claims encompass administering the elected compound to any patient for the prevention of neuropathic pain (as defined in page 3 of the specification). In order to prevent one must necessarily administer before the presence of disease and therefore administration of the elected compound in any patient population would then prevent neuropathic pain.

Jaio et al. teaches the administration of the elected compound for the treatment of inflammatory and immunoregulatory disorders (column 3 and claims 1-24).

Claims 2 and 4 remain rejected under 35 U.S.C. 102(e) as being anticipated by Butora et al (U.S. 7,390,803)

The claims encompass administering the elected compound to any patient for the prevention of neuropathic pain (as defined in page 3 of the specification). In order to prevent one must necessarily administer before the presence of disease and therefore administration of the elected compound in any patient population would then prevent neuropathic pain.

Jaio et al. teaches the administration of the elected compound for the treatment of inflammatory and immunoregulatory disorders (column 3 and claims 1-2).

Response to Applicant's Remarks

Applicant alleges that prevention of neuropathic pain is not claimed, but rather the claims are drawn to the treatment of neuropathic pain. In support of this allegation, Applicant points the Examiner to page 3, lines 7-8 which state "CCR2 antagonists can be used to treat, ameliorate and/or prevent neuropathic pain."

This is not found persuasive. Applicant is guided to paragraph [2282] which states "As used herein, the term 'treatment' refers both to the treatment and to the prevention or prophylactic therapy of

the mentioned conditions..." Therefore, the instant invention is drawn to the prevention of neuropathic pain, in light of the definition of "treatment" found in the instant specification.

Applicant alleges that the above cited references are drawn to the treatment or prevention of inflammatory and immunoregulatory disorders and as such one would not expect these disorders to be accompanied by pain.

Applicant fails to advance any specific reasons or evidence aside from Counsel's own allegations, in support of this position. This assertion by Counsel is an unsupported allegation and fails to take the place of evidence in the record. Statements of this nature are clearly unpersuasive in accordance with guidance provided at MPEP 2145, which states "The arguments of counsel cannot take the place of evidence in the record."

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 2 and 4 remain provisionally rejected on the ground of nonstatutory double patenting over claims 1, 7 and 12 of copending Application No. 10/260,008 and claim 1 of copending Application No. 11/587,448. This is a provisional double patenting rejection since the claims have not yet been patented.

An obviousness-type double patenting rejection is appropriate where conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claims because the examined claim is either anticipated by, or would have been obvious over, the reference claims.

Although the conflicting claims are not identical, the patented claims and those of the present application are considered to be patentably distinct from each other. The reasons are as follows:

Both sets of claims are drawn to the use of the instantly claimed compounds. As discussed above, the claims encompass administering the elected compound to any patient for the prevention of neuropathic pain (as defined in page 3 of the specification). In order to prevent one must necessarily administer before the presence of disease and therefore administration of the elected compound in any patient population would then prevent neuropathic pain.

In view of the foregoing, the copending application claims and the current application claims are obvious variants.

Claims 2 and 4 remain rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 4-5 and 8-11 of U.S. Patent No. 7,230,008 and claims 1-24 and 25-27 of U.S Patent No. 6,812,234 and claims 1-22 of U.S. Patent No. 7,393,844 and claims 1-24 of U.S. Patent No. 7,166,614 and claims 1-2 of U.S. Patent No. 7,390,803.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are embraced by the patented claims.

Both set of claims are directed to use of the same compounds. Both sets of claims are drawn to the use of the instantly claimed compounds. As discussed above, the claims encompass administering the elected compound to any patient for the prevention of neuropathic pain (as defined in page 3 of the specification). In order to prevent one must necessarily administer before the presence of disease and therefore administration of the elected compound in any patient population would then prevent neuropathic pain.

In view of the foregoing, the copending application claims and the current application claims are obvious variants.

Response to Applicant's Remarks

Applicant alleges that the instant double patenting rejections do not claim the treatment of neuropathic pain and are generally directed to inflammatory diseases, immunoregulatory diseases and rheumatoid arthritis, none of which are related to neuropathic pain.

This is not found persuasive. Applicant's definition of treatment includes prevention, as stated in the response above, therefore in order to prevent one must necessarily administer before the presence of disease and therefore administration of the elected compound in any patient population would then prevent neuropathic pain. Thus, the above double patenting rejections are maintained.

Conclusion

No claim is found to be allowable.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANNA PAGONAKIS whose telephone number is (571)270-3505. The examiner can normally be reached on Monday thru Thursday, 9am to 5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brandon Fetterolf can be reached on 571-272-2919. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AP

/Brandon J Fetterolf/
Primary Examiner, Art Unit 1642